ACC.13
62nd Annual Scientific Session & Expo
TCT@ACC-i2

E1207
JACC March 12, 2013
Volume 61, Issue 10

Chronic CAD/Stable Ischemic Heart Disease

MULTICENTER, PROSPECTIVE, RANDOMIZED, SINGLE BLIND, CONSECUTIVE ENROLLMENT EVALUATION A NOVOLIMUS-ELUTING CORONARY STENT SYSTEM WITH BIOABSORBABLE POLYMER COMPARED TO A ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM: 6-MONTH ANGIOGRAPHIC AND IVUS RESULTS AND 24- MONTH CLINICAL: THE EXCELLA BD STUDY

Poster Contributions
Poster Sessions, Expo North
Monday, March 11, 2013, 9:45 a.m.-10:30 a.m.

Session Title: Therapeutic Approaches in Chronic CAD and Stable Ischemic Heart Disease
Abstract Category: 11. Chronic CAD/Stable Ischemic Heart Disease: Therapy
Presentation Number: 1281-63

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Background: To evaluate the safety and effectiveness of the Elixir DESyneTM BD Novolimus Eluting Coronary Stent System (CSS) with a bioabsorbable polymer compared to the Endeavor Zotarolimus Eluting Coronary Stent System through the assessment of clinical, angiographic, and IVUS endpoints.

Methods: 149 patients were randomized 3:1, either to the Elixir DESyne BD Novolimus Eluting CSS loaded with 5mcg per mm of stent length of Novolimus, a sirolimus metabolite, eluted via a bioabsorbable polylactide-based polymer, or to the Endeavor Zotarolimus-eluting CSS loaded with 10mcg per mm of stent length of Zotarolimus eluted via a durable polymer. All patients were analyzed for the primary endpoint of in-stent late lumen loss (LLL) assessed by QCA at 6 months. Moreover, all patients underwent evaluation for secondary endpoints including a Device-orientated Composite Endpoint (DoCE) defined as: cardiac death, MI not clearly attributable to a non-intervention vessel, and clinically-indicated target lesion revascularization; clinically-indicated Target Vessel Revascularization (TVR), and stent thrombosis at 1, 6, 9, and 12 months and annually through 5 years. Lesions were also evaluated for QCA endpoints at 6 months including: in-segment LLL, percent diameter stenosis, and angiographic binary restenosis (ABR) (≥50%). A subset of patients underwent intravascular ultrasound (IVUS) evaluation including percent (%) neointimal obstruction at 6 months.

Results: The study met the primary endpoint demonstrating both non-inferiority and superiority of the DESyne BD compared to the control (0.12±0.15 vs 0.67±0.47, p<0.001), additionally, in-stent ABR was significantly lower for DESyne BD (0% vs 7.9%, p=0.003). Excellent clinical results at 6 months were demonstrated for both devices (DoCE 2.7% vs. 3.2%, p= 1.00). Clinical results through 24 months and complete QCA and IVUS results will be presented.

Conclusions: This randomized study evaluating the DESyne BD CSS met the non-inferiority endpoint and also demonstrated superiority for in-stent LLL as compared to the concurrent control. The clinical results through 24 months and complete QCA and IVUS results will be presented.